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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,023	12/19/2001	Guy Scott Bristol	539.337.2.1	5876
22859 7590 02/08/2007 INTELLECTUAL PROPERTY GROUP			EXAMINER	
FREDRIKSON & BYRON, P.A.			FRENEL, VANEL	
200 SOUTH SIXTH STREET SUITE 4000 MINNEAPOLIS, MN 55402			ART UNIT	· PAPER NUMBER
			3627	
SHORTENED STATUTORY PERIO	OD OF RESPONSE	MAIL DATE	DELIVERY MODE	
2 MONTHIS		02/09/2007	DADED	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Application No.	Applicant(s)	 			
Office Action Summary		10/025,023	BRISTOL, GUY S	BRISTOL, GUY SCOTT			
		Examiner	Art Unit				
		Vanel Frenel	-3627				
Period fo	The MAILING DATE of this communication apor Reply	pears on the cover sheet v	with the correspondence add	dress			
WHIC - Exte after - If NC - Faill Any	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING Designs of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. Of period for reply is specified above, the maximum statutory period rere to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUN 136(a). In no event, however, may a will apply and will expire SIX (6) MC e, cause the application to become A	ICATION. The reply be timely filed ONTHS from the mailing date of this contained by the c	, ,			
Status			•				
1)[[]	Responsive to communication(s) filed on 20 N	November 2006		•			
		s action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
٠,١	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims		,				
·		Indication					
	Claim(s) <u>1,2 and 4-74</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.						
	Claim(s) is/are allowed.	WIT HOTH CONSIDERATION.					
·	Claim(s) <u>1-2, 4-74</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
	Claim(s) are subject to restriction and/o	or election requirement					
ا (۵	are subject to restriction and/	or election requirement.					
Applicati	ion Papers						
9)[The specification is objected to by the Examine	er.					
10)[The drawing(s) filed on is/are: a) acc	cepted or b) objected to	by the Examiner.				
	Applicant may not request that any objection to the	drawing(s) be held in abeya	nce. See 37 CFR 1.85(a).	•			
	Replacement drawing sheet(s) including the correct	ction is required if the drawing	g(s) is objected to. See 37 CF	R 1.121(d).			
11)	The oath or declaration is objected to by the E	xaminer. Note the attache	ed Office Action or form PT	O-152.			
Priority ι	under 35 U.S.C. § 119						
12)	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C.	§ 119(a)-(d) or (f).				
	☐ All b)☐ Some * c)☐ None of:						
	1. Certified copies of the priority documen	ts have been received.	•				
	2. Certified copies of the priority documen	ts have been received in .	Application No				
	3. Copies of the certified copies of the price	ority documents have been	n received in this National S	Stage			
	application from the International Burea	u (PCT Rule 17.2(a)).	•	-			
* 5	See the attached detailed Office action for a list	of the certified copies no	t received.				
	•	•					
		•		•			
Attach	*(a)						
Attachmen	e of References Cited (PTO-892)	A)	Cumman, (DTO, 440)				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) 📋 Interview Paper No	Summary (PTO-413) (s)/Mail Date				
3) 🔲 Inform	mation Disclosure Statement(s) (PTO/SB/08)	5) D Notice of	Informal Patent Application				
Pape	r No(s)/Mail Date	6) 🔲 Other:	<u></u> .				

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DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Amendment filed on 11/20/06. Claims 1, 7, 10, 12, 18, 31, 41, 47, 48, 50, 63 and 74 have been amended. Claim 3 has been cancelled. Claims 1-2 and 4-74 are pending.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-2, 4-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al (5,781,442) in view of Vasko (5,871,465), for substantially the same reasons given in the prior Office Action, and incorporated herein. Further reasons are presented hereinbelow.
- (A) Claim 1 has been amended to recite the limitations of "therapeutic substance infusion", "adapted to permit a user to provide feedback to a therapeutic substance infusion device manufacturer regarding the operation of the one or more therapeutic substance infusion devices. However, these limitations have been clearly shown in Vasko, Fig.2; Col.5, lines 8-67).

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(B) Claim 7 has been amended to recite the limitation of "at least one", erase the article "the" and also erase an (s) in the word device. However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.

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- (C) Claims 10 and 48 have been amended to recite the limitation of "at least one". However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.
- (D) Claims 12 and 50 have been amended to erase the article "the". However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.
- (E) Claim 18 has been amended to erase the words "one of" and delete an "s" in the word claim. However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.
- (F) Claims 31 and 63 have been amended to recite the limitation of "information". However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.

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(G) Claim 41 has been amended to recite the limitation of "therapeutic substance infusion". However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.

- (H) Claim 47 has been amended to recite the limitation of "manufacturers". However, this changes does not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.
- (I) Claim 74 has been amended to recite the limitations of" a server connected to said internetwork, wherein", "and", "therapeutic substance infusion", "adopted to allow", and "adopted to allow". However, these change do not affect the breadth and the scope of the claim as presented in the previous Office Action, and incorporated herein.
- (J) Claims 2, 4-6, 8-9, 11, 13-17, 19-30, 32-40, 42-46, 49, 51-62 and 64-73 are not been amended are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

Response to Arguments

- 4. Applicant's arguments filed on 11/20/06with respect to claims 1-2, and 4-74 have been fully considered but they are not persuasive.
- (A) At pages 17-20 of the response filed on 11/20/06, Applicant's argues the followings:

- (1) There is no suggestion in either of the references that they combined in the manner suggested by the Examiner.
- (2) Neither Engleson nor Vasko disclose communication with a drug pump manufacturer such as required by claim 1.
- (3) The request of two references (US Patent No. 5,895,371) and (US. Application No.2005/0021297) cited in the prior Office Action to be acknowledged in the PTO-892.
- (B) With respect to Applicant's first argument, Examiner respectfully submitted that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a *prima facie* case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention.

Rather, Applicant does not point to any specific distinction(s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111(b) states, "A general allegation that the claims define a

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patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the requirements of this section." Applicant has failed to specifically point out how the language of the claims patentably distinguishes them from the applied references. Also, arguments or conclusions of Attorney cannot take the place of evidence. In re Cole, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); In re Schulze, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); Mertizner v. Mindick, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

In addition, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. However, although the Examiner agrees that the motivation or suggestion to make modifications must be articulated, it is respectfully contended that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves.

References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

The Examiner is concerned that Applicant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

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(i) obviousness does not require absolute predictability;

- (ii) non-preferred embodiments of prior art must also be considered; and
- (iii) the question is not <u>express</u> teaching of references, but what they would suggest. Therefore, Applicant's argument is not persuasive and the rejection is hereby sustained.
- (C) With respect to Applicant's second argument, Examiner respectfully submitted that He relied upon the clear and unmistakable teachings of Vasko See Col.11, lines 51-67 to Col.12, line 11 which correspond to Applicant claimed feature. Therefore, Applicant's argument is not persuasive and the rejection is hereby sustained.
- (D) With respect to Applicant third argument, Examiner thanked Applicant for the inadvertent mistake of these prior arts (US Patent No. 5, 895, 371) and (US Application No.2005/0021297) in the PTO- 892. For purpose of clarity, Examiner will cite these prior arts to Applicant's as requested in the Amendment.
- 5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not the applied art teaches medical treatment apparatus and method (5,895,371) and therapy management techniques for an implantable medical device (2005/0021297).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 571-272-6769. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zeender Ryan Florian can be reached on 571-272-6790. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Archen Joseph Frody Promary Examiner, AU 3627

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V. F

January 31, 2007

Hrohen Joseph Lidy Primary Examiner, AU 3627